No. 23-55742

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PAINTERS & ALLIED TRADES DISTRICT COUNCIL 82 HEALTH, ET AL.,
Plaintiff-Appellee,

v.

TAKEDA PHARMACEUTICAL COMPANY LIMITED, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court for the Central District of California, No. 2:17-cv-07223, Hon. John. W. Holcomb

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Defendants-Appellants, by and through their undersigned counsel, hereby certify the following:

Takeda Pharmaceuticals U.S.A., Inc. is a directly-owned subsidiary of: (a) Takeda Pharmaceutical Company Limited, a publicly held Japanese company (4502:JP; TAK:NYSE); and (b) Takeda Pharmaceuticals International AG.

Takeda Pharmaceutical Company Limited is a publicly held entity traded on the Tokyo Stock Exchange and the New York Stock Exchange and has no parent company. No publicly held company owns 10% or more of its stock.

Eli Lilly and Company is a publicly held entity traded on the New York Stock Exchange and has no parent company. No publicly held company owns 10% or more of its stock.

January 19, 2024

Respectfully submitted,

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**I certify that the additional listed party concurs with the filing of this statement.*

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

In this first-of-its-kind RICO class action, the district court certified a class on the theory that Plaintiff will be able to prove in a single stroke that tens of thousands of third-party payors (TPPs) were injured by Defendants' alleged failure to disclose the health risks of Actos, a prescription medication for diabetes. In so holding, the district court broke with every other court that has considered this kind of class action. All other courts have correctly denied class certification because, in cases like this one in which causation and injury depend on decisions of individual physicians about which medication to prescribe to individual patients, individual inquiries into causation and injury will overwhelm common inquiries at trial.

Plaintiff is a small employee benefit plan that pays for its members' medical costs. Plaintiff does not claim Actos caused any adverse health effects to its plan members, nor does it seek recovery for any prescriptions that allegedly resulted in personal injury. Instead, it claims that if not for Defendants' alleged disclosure failures, physicians would not have *written* as many Actos prescriptions, and as a result, the proposed class of TPPs would not have *paid* for as many prescriptions. Plaintiff concedes, however, that millions of prescriptions still would have been written even in the absence of the alleged disclosure failures, and it lacks any means of distinguishing those prescriptions from the so-called "excess" prescriptions that allegedly would not have been written. The district court thus recognized that "a

real and significant risk exists" that "individualized inquiries" into which prescriptions were and were not impacted by the alleged disclosure failures will "swamp" common inquiries at trial. 1-ER-29. Despite that risk, the court found that Plaintiff "eke[d] out a victory" on class certification and certified a class seeking $7 billion in alleged damages. 1-ER-31. In so doing, the court committed at least four reversible errors.

First, the court failed to conduct the necessary "rigorous analysis" of the expert evidence Plaintiff offered to satisfy Rule 23(b)(3)'s predominance requirement. The district court found that Plaintiff satisfied that requirement by offering expert estimates that (i) 57% of Actos prescriptions were "fraudulently induced" and (ii) 98.5% of class members likely paid for a fraudulently-induced prescription. But Defendants offered extensive evidence that these estimates are based on faulty assumptions that render them incapable of proving causation and injury on a classwide basis. Rather than resolving this pivotal dispute, the district court simply took Plaintiff's expert analysis "at face value" and refused to consider "any … contradicting evidence or testimony from Takeda's experts." 1-ER-22 n.88. If the court had conducted the rigorous analysis of Plaintiff's evidence that this Court's precedent requires, it could not have found that this evidence satisfied the predominance requirement. Indeed, the Second Circuit has twice held that similar expert evidence fails as a matter of law to prove predominance. *See Sergeants*

Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP, 806 F.3d 71, 90-92 (2d Cir. 2015); *UFCW Local 1776 v. Eli Lilly & Co.* (*Zyprexa*), 620 F.3d 121, 126 (2d Cir. 2010).

Second, the district court erred by certifying a class despite the thousands of individualized challenges to causation and injury Defendants will raise at trial. The district court recognized that Defendants will "avail themselves of a TPP-by-TPP causation defense using doctor-by-doctor testimony" to show that vast numbers of prescriptions were unaffected by the alleged disclosure failures. 1-ER-30. The court also acknowledged that "[i]t remains an open question whether a class of TPPs may successfully leverage common evidence of the kind offered here ... *without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones*." 1-ER-28 (emphasis added). But instead of resolving that "open question" by considering all the evidence Defendants will present when the case is ready for trial, the court assessed predominance based solely on the evidence each side deposited into the class certification record, observing that "[a]s the tally stands, individualized issues would not predominate over but-for causation *if the trial was held today*." 1-ER-31 (emphasis added). That approach cannot be reconciled with binding precedent requiring courts to consider "the spectre of class-member-by-class-member adjudication" in evaluating predominance, even if a

defendant provides as few as "two … examples" to illustrate its individualized defenses. *Van v. LLR, Inc.*, 61 F.4th 1053, 1068-69 & n.13 (9th Cir. 2023).

Third, the district court erred by disregarding countless individual inquiries that will be necessary to distinguish uninjured class members from allegedly injured ones. It is undisputed that at least *some* class members were uninjured and that Plaintiff has no "common evidence" capable of separating these uninjured TPPs from any injured ones. The only way to identify these unharmed TPPs is to comb through tens of thousands of TPPs one by one and analyze the individual decisions of the individual physicians who wrote the relevant prescriptions. Those individual inquiries independently defeat predominance.

Fourth, the district court improperly dismissed two other reasons why this litigation is unsuited for class treatment. It erred in finding that Plaintiff satisfied Rule 23(b)(3)'s superiority requirement, which is insurmountable absent a manageable plan for trying this case notwithstanding the need for individualized evidence and testimony from thousands of TPPs and tens of thousands of witnesses. Neither Plaintiff nor the district court provided any such plan. Moreover, certification of a class against Defendant Eli Lilly and Company was especially improper. Actos was manufactured by the Takeda Defendants, and Lilly merely promoted the medication under an agreement that ended in 2006. Yet Plaintiff proposes a monolithic class running from 1999 to 2010, and Plaintiff's averages-

driven mathematical approach to proving causation and injury is irreconcilable with proving those elements for a limited time period.

The district court's novel class certification order should be reversed.

JURISDICTIONAL STATEMENT

The district court had federal-question jurisdiction over Plaintiff's RICO claims. 28 U.S.C. § 1331. On May 24, 2023, the district court granted in part the motion for class certification. On June 7, Defendants timely petitioned to appeal under Federal Rule of Civil Procedure 23(f). This Court granted the petition and has jurisdiction under 28 U.S.C. § 1292(e).

ISSUES PRESENTED

1. Whether the district court erred in certifying a first-of-its-kind class action without rigorously analyzing the purported common evidence of causation and injury or considering the conflicting evidence offered by Defendants.

2. Whether the district court erred in limiting its predominance analysis to the evidence as it existed at class certification rather than considering "the *spectre* of class-member-by-class-member adjudication" once the record is fully developed for trial. *Van*, 61 F.4th at 1069 (emphasis added).

3. Whether the district court erred in dismissing the need for individualized inquiries into injury despite Plaintiff's lack of any method for identifying admittedly uninjured class members.

4. Whether the district court erred in assessing superiority and in bypassing Lilly-specific issues that should have foreclosed certifying a 1999-to-2010 class.

STATUTORY ADDENDUM

Pursuant to Circuit Rule 28-2.7, pertinent federal rules are set forth in an addendum to the brief.

STATEMENT OF THE CASE

A. Actos

Actos—the brand-name version of the prescription medication pioglitazone—is a widely-used oral treatment for type-2 diabetes. 3-ER-340, 397. Like all prescription medications, Actos has both risks and benefits and thus was heavily regulated by the U.S. Food and Drug Administration ("FDA") throughout the relevant period. *See* 21 U.S.C. §§ 301 *et seq*. The FDA approved Actos in July 1999. 3-ER-341. Actos enjoyed exclusivity until August 2012, when generic pioglitazone and pioglitazone combination products entered the market. 3-ER-341. Pioglitazone remains FDA-approved to treat type-2 diabetes today.

Plaintiff alleges—and Defendants strenuously deny—that Actos is associated with a slightly elevated risk of developing bladder cancer. The possibility of such a connection was disclosed on Actos's FDA-approved label beginning in 1999, when Actos first entered the market, and those disclosures were later updated after new scientific studies were completed. *See* 3-ER-341. Based on its ongoing review of

the evolving scientific literature, the FDA issued the following series of communications about bladder cancer and other potential risks of taking Actos:

- Beginning in July 1999, Actos's original FDA-approved label disclosed the occurrence of potential Actos-induced bladder tumors in animal studies. 3-ER-341.

- In August 2006, the FDA approved an updated label containing information on two recently completed studies in which patients taking Actos reported a slightly higher number of bladder cancers as compared to those taking a placebo. 3-ER-341-42.

- In August 2007, the FDA approved updated labels for Actos and a different medication—Avandia—to include a warning about an elevated risk of congestive heart failure. 3-ER-343-44.

- In September 2010, the FDA issued a Drug Safety Communication noting it was reviewing new data regarding a potential association between Actos and bladder cancer. 3-ER-342.

- In June 2011, the FDA issued a Drug Safety Communication indicating that the use of Actos "for more than one year may be associated with an increased risk of bladder cancer." 3-ER-342. This was followed on August 4, 2011 by FDA approval of updated labels for Actos and other pioglitazone-containing medications. 3-ER-342.

The FDA-approved Actos label thus has *always* contained information about potential bladder cancer risks. Weighing these risks against the benefits of taking Actos is the responsibility of licensed physicians who determine whether to prescribe Actos and other medications for their patients. 3-ER-345. These physicians bring their own individual perspectives to bear in deciding which medications to prescribe, including their prior experience with these medications, their knowledge of potential side effects, and their views on alternative treatment

options for any given patient. 3-ER-340, 345, 396-97. Physician decisions about whether to prescribe Actos thus are highly individualized, not one-size-fits-all. To this day, physicians continue to write large numbers of Actos prescriptions despite widespread public attention to the purported association with bladder cancer. *E.g.*, 3-ER-343.

Reimbursement for Actos prescriptions likewise depends on individualized factors. In most cases, prescription costs are spread across multiple parties, including TPPs, manufacturers, pharmacies, pharmacy benefit managers, and patients. 3-ER-346, 347-49. TPPs—which include insurance companies, healthcare benefit providers, and other health plans—vary greatly in their size, structure, and patient population. Many TPPs are small employer plans covering fewer than 50 plan members; others are large national insurance plans; and still others are union plans organized under ERISA, Medicare Part D plans, or Medicaid managed care plans. 2-ER-58; 4-ER-486; *see also* 3-ER-367 & n.112.

B. Plaintiff's Lawsuit

Defendants vigorously dispute that Actos causes bladder cancer, and with good reason. The FDA has found "insufficient data" to make a conclusive determination, 2-ER-159, and juries in five out of nine personal-injury cases have found that Actos did not cause those patients' bladder cancer, Dkt. 202, Takeda's Opp'n to Mot. to Estop 5 & n.3.

Personal injury issues, however, are not asserted here. This case instead involves a civil RICO claim brought by Painters and Allied Trades District Council 82 Health Care Fund ("Plaintiff"), a Minnesota-based TPP. Plaintiff, on behalf of a class of thousands of TPPs, alleges that Defendants concealed the potential association between Actos and bladder cancer from patients and doctors. 1-ER-7-8. According to Plaintiff, the possibility that Actos might cause bladder cancer did not become widely known until the FDA's September 2010 Drug Safety Communication. 1-ER-8. Plaintiff contends that, during a class period running from July 1999 through September 2010, Defendants' alleged concealment of purported bladder cancer risks caused doctors to write—and TPPs to pay for—more Actos prescriptions than they otherwise would have. 1-ER-8.

This is not the first time Plaintiff's RICO claim has come before this Court. In 2019, the Court reversed the district court's Rule 12(b)(6) dismissal of Plaintiff's claim for failure to plead proximate causation. *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co.*, 943 F.3d 1243, 1248 n.6 (9th Cir. 2019). Although this Court found that Plaintiff plausibly alleged proximate causation at the pleading stage, it did not address whether Plaintiff could *prove* either proximate causation, but-for causation, or injury on the merits, let alone whether Plaintiff could do so on a classwide basis. *See id.* at 1248; *see also In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 34 (1st Cir. 2013) ("but-for causation and

proximate causation … are two quite distinct questions"). This Court "express[ed] no opinion on Plaintiffs' chances of success in this litigation," and predicted that "discovery" would be necessary for Plaintiff "to determine with specificity exactly which doctors relied on Defendants' alleged misrepresentations." *Painters*, 943 F.3d at 1260.

C. Plaintiff's Expert Report

Plaintiff chose not to develop any evidence regarding which doctors relied on the alleged disclosure failures during discovery. Instead, Plaintiff attempted to sidestep these individual inquiries by offering probability estimates generated by its damages expert, Dr. William Comanor. According to those estimates, 43.3% of Actos prescriptions written between 1999 and 2010 were "fully informed" and would have been written "even in the absence" of the alleged disclosure failures, and the other 56.7% would not. *See* 4-ER-539.

Comanor based these estimates on a crude extrapolation from Actos's December 2013 market share. He began by claiming that the medical community was not "fully informed" of the potential risks of Actos until December 2013, at which point Actos-containing products had a 4.72% share "of the total market for anti-diabetic drugs." 4-ER-535. He then applied that 4.72% market share to the 1999-to-2010 period to "estimate the 'but-for' volumes of Actos prescriptions" that supposedly would have been written "had the bladder cancer risk been widely known

throughout the damages period." *Id.* In other words, he assumed that in the but-for world, Actos would have accounted for 4.72% of the total market for each year from 1999-2010; any prescriptions above that amount were counted as "excess." On that basis, he inferred that approximately 57% of Actos prescriptions would not have been written in the but-for world. *See* 4-ER-553; 1-ER-22.

Comanor thus assumed that every single Actos prescription written between 1999 and 2010 *above* the 4.72 percent market share that Actos maintained in December 2013 was caused solely by the alleged disclosure failures. 3-ER-386-87, 3-ER-407-09. That assumption, however, is concededly faulty. *See* 3-ER-386-87, 3-ER-407-09. Comanor admitted at his deposition that the decline in Actos prescriptions over time was not entirely "due to the dissemination of information" about bladder cancer. 3-ER-265-66. He also ignored the fact that the scientific research that led the FDA to approve an updated Actos label in 2006, and later to issue its September 2010 bladder cancer warning, could not have been disclosed in 1999 because they were not completed until much later. *See* 3-ER-341-42.

Comanor's estimates also present a second problem: identifying which specific TPPs paid for "fraudulently-induced" prescriptions. Comanor admitted that his class-wide probability estimates "obviously" cannot identify which prescriptions were fraudulently induced because they "can't say what an individual physician would do with respect to any particular patient and their prescribing." 3-ER-315-

16. And even taking his 57% estimate at face value, a TPP that paid for just a single Actos prescription has only "a 42% chance of paying for one that was fraudulently induced." 4-ER-541.

Comanor attempted to assume these problems away by claiming that, if a TPP paid for five "independent" Actos prescriptions during the class period, and if each of those prescriptions had a 57% chance of being fraudulently induced, there is a 98.5% chance that the TPP paid for at least one "fraudulently-induced" prescription. 1-ER-22 & n.90. The prerequisite of five "independent" prescriptions, however, requires its own set of fact-intensive individualized inquiries. Comanor's 98.5% calculation "assum[es]" that fraudulently-induced prescriptions are randomly distributed throughout the class, or in other words, that "the presence of a claim based on fraudulent information does not alter the probability of the same outcome in another claim." 4-ER-539-40. But physicians do not hand out Actos prescriptions at random. Instead, they rely on recurring factors such as their own individual training, experience, preferences, knowledge of the scientific literature, and assessments of the risks of various treatment options. 3-ER-368-69. Comanor thus concedes that determining whether Actos prescriptions were "independent" of each other requires a study of "prescribing habits and how physicians treat different patients." 3-ER-319-20. Comanor "ha[s] not done" that fact-intensive, physician-specific inquiry. 3-ER-320.

D. The Class Certification Order

The district court considered two proposed classes: (i) a class of California consumers who took Actos during the class period, and (ii) a nationwide class of TPPs that paid for five or more "independent" Actos prescriptions during that period.

The district court denied certification of the consumer class on predominance grounds, concluding that "a muddled mix of common and individualized evidence would be needed to resolve the elements of causation and reliance" given the "highly individualized" nature of whether additional bladder cancer disclosures would have mattered to individual patients or their physicians. 1-ER-36-37, 44. Although those same individualized concerns apply to TPPs, and although the court worried that "[i]t remains an open question whether a class of TPPs may successfully leverage common evidence of the kind offered here … without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones," 1-ER-28, the court found that Plaintiff "eke[ed] out a victory" as to the TPP class, 1-ER-31.

The court distinguished the consumer class from the TPP class based on its impression that, "for the latter class, Plaintiffs offer a compelling regression analysis to circumvent [the need for] individualized evidence." 1-ER-44. Specifically, the court assumed that Comanor used "an econometric regression model" to estimate that "had a bladder cancer warning been issued from the beginning, TPPs would

have paid for 57% fewer Actos prescriptions during the class period." 1-ER-8-9. As noted above, however, Comanor actually used a crude market-share extrapolation—not a regression model—to generate his 57% estimate. Moreover, the court declined to scrutinize Comanor's 57% estimate or consider Defendants' arguments that it rests on false and unsubstantiated assumptions. Instead, the court simply "t[ook] Comanor's report at face value" and refused to "prejudge its accuracy" or consider "any ... contradicting evidence or testimony from Takeda's experts." 1-ER-22 & n.88.

Even after taking Comanor's probability estimates "at face value," the district court recognized that "a real and significant risk exists that individualized factual determinations would swamp common ones on the question of but-for causation." 1-ER-29. That is because, notwithstanding Comanor's estimates, Defendants retain the right to introduce individualized evidence from "individual prescribing physicians … [who] might testify that they would have continued to prescribe Actos, notwithstanding the bladder cancer risk." *Id.* For instance, Defendants deposed the individuals who prescribed Actos to the proposed representatives of the consumer class, and both testified that additional disclosures would have made no difference to them. 1-ER-31. The court nonetheless dismissed these representative examples on the theory that, "if the trial was held today," and if predominance is assessed based on a simple "tally" of the volume of common and individualized evidence

deposited into the class certification record, Defendants' two illustrative examples standing alone would not predominate. *Id*.

The court also recognized that "it is not known at this time which specific TPPs managed to avoid paying for any fraudulently induced prescriptions" and that Plaintiff cannot identify these unharmed TPPs without conducting full-blown individual trials. 1-ER-22. But the court brushed this problem away by stating that, "*[t]aking Dr. Comanor's analysis at face value*," it implies that "one would expect—statistically speaking—that Takeda and Lilly could dispute injury ... for only about 1.5% of the class." *Id*. (emphasis added).

SUMMARY OF ARGUMENT

The class certification order rests on at least four reversible errors.

I. The district court erred in taking "at face value" Comanor's all-important estimates that 57% of prescriptions were fraudulently induced and at least 98.5% of class members were injured. Those estimates are Plaintiff's only hope of demonstrating predominance; without them, individualized inquiries into causation and injury would overwhelm common inquiries at trial. Yet, rather than conducting a rigorous analysis of those estimates or resolving Defendants' arguments that they rest on faulty assumptions, the court allowed a $7 billion class action to proceed. This approach not only breaks with controlling precedent, but also invites future lawsuits where similarly faulty estimates could be manufactured to support

certification and extort settlements without any meaningful evaluation of their deficiencies.

If the district court had conducted the "rigorous analysis" of Comanor's estimates required by this Court's precedent, it could not have found that they satisfy the predominance requirement. Those estimates rely on the same sort of crude market-share extrapolation that the Second Circuit twice has rejected as insufficient to support certification of TPP classes. *See Sergeants*, 806 F.3d at 90-92; *Zyprexa*, 620 F.3d at 135-36. Furthermore, Plaintiff cannot rely on Comanor's estimates without proving that each TPP paid for at least five "independent" prescriptions that are causally unlinked, and making that showing requires exactly the kind of prescription-specific individualized inquiries that defeat predominance.

II. The district court also erred in certifying a class despite the individual challenges to causation and injury Defendants will raise at trial. The court recognized that Defendants are entitled to rely on testimony from "individual prescribing physicians" to "qualify, discredit, or reject Plaintiffs' common evidence." 1-ER-29. The court also acknowledged that "[i]t remains an open question" whether individualized questions of fact will "overwhelm" common questions at trial. *See* 1-ER-28. The court should have stopped there: if that question remains open, then by definition Plaintiff failed to carry its burden of proving that common issues will predominate over individual ones.

Instead of holding Plaintiff to its burden, the court flipped the burden to Defendants to *disprove* predominance and held that Defendants failed to do so because, "if the trial was held today," the representative examples of individualized causation defenses offered by Defendants at the certification stage would not by themselves overwhelm common questions. 1-ER-31. That approach cannot be reconciled with *Van v. LLR, Inc.*, 61 F.4th 1053 (9th Cir. 2023), which holds that *plaintiffs* bear the burden of proving individualized defenses will not predominate, and that a few representative examples of individualized defenses will suffice to "summon[] the spectre of class-member-by-class-member adjudication." *Id.* at 1067-69 & n.11.

III. The court erred again by certifying a class notwithstanding the thousands of individual inquiries that will be necessary to separate uninjured class members from allegedly injured ones. Plaintiff does not deny that the class contains at least *some* uninjured TPPs. Plaintiff therefore bears the burden of showing that it can "segregate the uninjured from the truly injured" through an efficient process that will not cause individual inquiries to predominate over common ones. *In re Rail Freight Fuel Surcharge Antitrust Litig.* (*Rail Freight II*), 934 F.3d 619, 624-25 (D.C. Cir. 2019). No such process exists here. Even Plaintiff admits that "it is true it will take individual inquiry to determine if an individual TPP was injured." Dkt. 258, Pl.'s Class Cert. Reply 11:10-11. Although the district court observed that only a

small number of uninjured class members exist *if* Comanor's estimates are correct, 1-ER-22, that is no consolation because—even accepting Comanor's faulty estimates—the only way to identify those unharmed TPPs is to comb the entire class using individualized evidence. That alone defeats predominance.

IV. The TPP class has two other significant flaws that should have foreclosed certification. *First*, the district court's two-paragraph analysis of the superiority requirement failed to hold Plaintiff to its burden of showing it has a manageable trial plan. Plaintiff offered no trial plan whatsoever, confirming that the only plan here is to extort a settlement before a "nightmare" trial that will feature testimony and evidence about countless doctors writing millions of prescriptions reimbursed by thousands of TPPs. 1-ER-15. *Second*, class-wide proceedings against Lilly are especially untenable. Comanor's model relies on averages spanning from 1999 to 2010, utterly ignoring the fact that Lilly stopped promoting Actos in 2006.

STANDARD OF REVIEW

This Court reviews class certification orders for abuse of discretion, *see Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 663 (9th Cir. 2022) (en banc), reviews underlying legal questions *de novo*, *see Stromberg v. Qualcomm Inc.*, 14 F.4th 1059, 1066 (9th Cir. 2021), and reviews underlying findings of fact for clear error, *see id*.

ARGUMENT

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (quotation omitted). Yet the decision below promises to turn every drug-labeling dispute into a multi-billion dollar RICO class action with treble damages—not just in the rare case where a RICO plaintiff has a meritorious theory of classwide harm, but in virtually every case where a plaintiff can find an "expert" willing to offer a collective theory of causation and injury, at which point the threat of colossal liability often will force defendants to settle. As shown below, that is not the law of class actions or RICO.

I. The District Court Erred By Accepting "At Face Value" Plaintiff's Inadequate Class-Wide Evidence.

Whether common questions will predominate in this litigation turns on whether Dr. Comanor's probability estimates are capable of fairly and accurately resolving issues that by their nature are highly individualized—RICO causation and injury—"in one stroke." *Wal-Mart*, 564 U.S. at 350. But rather than engage in the "rigorous analysis" of that question required by Rule 23, *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 980 (9th Cir. 2011), the district court punted and took Comanor's evidence "at face value" without "prejudg[ing] its accuracy." 1-ER-22 & n.88.

That decision was error twice over. *First*, the class certification order should be reversed because the district court never conducted the rigorous analysis of Comanor's work that this Court's precedent requires. *Second*, certification should be reversed because Comanor's estimates not only rehash the same defective methodology that courts have rejected as insufficient in similar RICO class actions, but also raise their own additional host of individualized inquiries that swamp any common inquiries.

A. Predominance hinges on whether common evidence can resolve causation and reliance on a classwide basis.

"Causation lies at the heart of a civil RICO claim." *Poulos v. Caesars World, Inc.*, 379 F.3d 654, 664 (9th Cir. 2004). As this Court previously recognized, Plaintiff here can prove causation only by showing "exactly which doctors relied on Defendants' alleged misrepresentations" with respect to Actos during the class period, thus causing TPPs to pay for more prescriptions than they otherwise would have. *Painters*, 943 F.3d at 1260. Plaintiff has no alternative to proving reliance on those alleged misrepresentations because, "logically, a plaintiff cannot even establish but-for causation if *no one* relied on the defendant's alleged misrepresentation." *Id*. at 1259. Indeed, "if the person who was allegedly deceived by the misrepresentation[s] (plaintiff or not) would have acted in the same way regardless of the misrepresentation, then the misrepresentation cannot be a but-for … cause of the plaintiffs' injury." *Sergeants*, 806 F.3d at 87.

Plaintiff faces a "quite difficult" challenge in proving predominance despite these causation and reliance questions. *Id*. Plaintiff must prove causation and reliance for each individual class member because "[l]umping claims together in a class action does not diminish or dilute" the burden of proof. *Poulos*, 379 F.3d at 664. Furthermore, if individualized evidence will be necessary to establish causation and reliance, "individual issues then would overwhelm the common ones, making certification under Rule 23(b)(3) inappropriate." *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 268 (2014) (alterations in original) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 242 (1988)). As a result, courts deny certification of RICO class actions when individual inquiries into causation and reliance will be required. *See, e.g.*, *Sergeants*, 806 F.3d at 90-97 (individual issues predominated in RICO prescription drug class action where individual inquiries were necessary to determine causation and reliance); *Zyprexa*, 620 F.3d at 133-36 (same); *Poulos*, 379 F.3d at 665-66 (need for "individualized showing[s] of reliance" defeated predominance in RICO class action); *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 219-23 (2d Cir. 2008) (reversing certification of RICO class where individualized evidence was necessary to determine whether class members relied on fraudulent marketing campaign); *Andrews v. AT&T Co.*, 95 F.3d 1014, 1025 (11th Cir. 1996) (reversing certification of RICO class where class members would "have to show, on an individual basis, that they relied on the misrepresentations").

Plaintiff's only way around this obstacle to class certification is to provide "generalized proof" capable of fairly and accurately resolving issues of causation and reliance in one stroke. *Sergeants*, 806 F.3d at 87-90 ("[A] plaintiff seeking to certify a class of plaintiffs in a [RICO] § 1964(c) suit cannot succeed unless the proposed class can demonstrate by generalized proof that the defendant's misconduct was both the but-for cause and the proximate cause of each class member's injury."); *Zyprexa*, 620 F.3d at 131-32 ("In order to pursue their claims as a class … the putative class must be able to prove its theory of injury through generalized proof"). Providing such proof in the prescription drug context, however, is exceedingly difficult due to "the individualized nature of physicians' prescribing decisions." *Sergeants*, 806 F.3d at 89-90. Indeed, courts invariably find predominance lacking in cases like this one in which causation turns on the decisions of individual physicians about which medications to prescribe.[1]

[1] *See supra* p.21; *Andren v. Alere, Inc.*, 2018 WL 1920179, at *4-6 (S.D. Cal. Apr. 24, 2018) (denying certification in case involving "individual inquiries into each doctor's experience with the product"); *Saavedra v. Eli Lilly & Co.*, 2014 WL 7338930, at *8 (C.D. Cal. Dec. 18, 2014) (denying certification where "the existence and degree of Plaintiffs' claimed injury will differ based on each individual's (or the individual's physician's) consideration of" benefits and risk of a drug); *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 291 F.R.D. 13, 20-21 (D. Mass. 2013) (denying certification for claims based on alleged misrepresentations because plaintiffs' claims required "individual, plaintiff-specific determinations"); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 203-04 (D. Minn. 2003) (denying certification where "consideration of individualized issues such as dosage" was necessary).

B. The district court erred by taking Plaintiff's common evidence "at face value" rather than subjecting it to "rigorous analysis."

The district court found that Plaintiff provided the requisite "generalized proof" of causation and injury in the form of Comanor's estimates that (i) 57% of Actos prescriptions were fraudulently induced and (ii) 98.5% of TPPs likely paid for a fraudulently-induced prescription if they paid for five independent prescriptions. *See* 1-ER-8-9, 21-22. The district court simply accepted those estimates "at face value," 1-ER-22 & n.88, without considering Defendants' contrary evidence or subjecting Comanor's evidence to the "rigorous analysis" required by Rule 23. *See Ellis*, 657 F.3d at 982. That failure alone is reversible error. *See, e.g.*, *id.* at 982-84 (vacating certification order where district court failed to conduct a "rigorous analysis" of plaintiffs' expert evidence or consider defendants' contrary evidence); *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323-25 (3d Cir. 2008) (same).

In response to Comanor's 57% and 98.5% estimates, Defendants presented evidence that those estimates rest on false and unsubstantiated assumptions including (1) an admittedly false assumption that the alleged disclosure failures were the *only* reason Actos's market share declined over the fourteen-year period running from June 1999 to December 2013, and (2) an equally false assumption that the purported fraudulently-induced prescriptions were randomly distributed throughout

the class rather than concentrated among particular doctors and TPPs.[2] If those challenges to Comanor's estimates have merit, then Comanor's 57% and 98.5% claims are a mirage and therefore fail as a matter of law to provide viable common proof of classwide causation. *See, e.g.*, *Olean*, 31 F.4th at 666 n.9 (expert evidence cannot satisfy the predominance requirement if it "contain[s] unsupported assumptions" or is "inadequate to prove an element of the claim for the entire class"); *Sergeants*, 806 F.3d at 92-96 (expert evidence based on faulty assumptions failed to provide viable "generalized proof" of causation); *Zyprexa*, 620 F.3d at 135 (same).

The district court nonetheless failed to resolve these critical disputes. Instead, it accepted Comanor's evidence "at face value," declined to "prejudge its accuracy," and refused to consider "any contradicting evidence or testimony from Takeda's experts." 1-ER-22 & n.88. The court reasoned that "it is up to the finder of fact to weigh Comanor's evidence" and assess its accuracy at trial. *Id*.

That was reversible error. Rule 23 requires district courts to "make a rigorous assessment of the available evidence and the method or methods by which plaintiffs propose to use the [class-wide] evidence to prove the common question in one stroke." *Olean*, 31 F.4th at 666. This obligation often includes "[w]eighing conflicting expert testimony" and "[r]esolving expert disputes," *id*., as well as

[2] *See, e.g.*, *infra* pp.30-32, 34-37, 39-40 (discussing Defendants' evidence at greater length).

"judging the persuasiveness of the evidence presented," *Ellis*, 657 F.3d at 982. Indeed, declining to resolve expert disputes at the class certification stage "amounts to a delegation of judicial power to the plaintiffs, who can obtain class certification just by hiring a competent expert." *West v. Prudential Secs., Inc.*, 282 F.3d 935, 938 (7th Cir. 2002). Accordingly, where expert disputes bear on whether a plaintiff has satisfied Rule 23 requirements, courts must resolve those disputes under a preponderance of the evidence standard at the certification stage. *See, e.g.*, *Goldman Sachs v. Ark. Teachers Ret. Sys.*, 141 S. Ct. 1951, 1959, 1963 (2021) (requiring courts to resolve expert disputes over price impact under a preponderance standard in securities class actions); *Olean*, 31 F.4th at 665 ("plaintiffs must prove the facts necessary to [satisfy Rule 23 requirements] by a preponderance of the evidence"); *Hydrogen Peroxide*, 552 F.3d at 307, 320, 320-24 (fact and expert disputes relevant to Rule 23 requirements must be determined under a preponderance standard).

These principles apply with particular force here because Comanor's estimates are indispensable to the district court's predominance finding. Those estimates formed the basis of the court's conclusions that Defendants "could dispute injury . . . for only about 1.5% of the class," 1-ER-22, that "the number of uninjured TPPs appears to be *de minimis*," 1-ER-23, and that, as a result, "it is more likely than not that common questions of fact would predominate over individualized ones when it comes to injury," 1-ER-23. The court's failure to conduct a rigorous analysis

of those estimates or consider Defendants' contrary evidence requires reversal. *See, e.g.*, *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 194 (3rd Cir. 2020) (vacating class certification where district court refused to "weigh the competing [expert] evidence"); *Ellis*, 657 F.3d at 982 (vacating certification where district court failed to "judg[e] the persuasiveness of the [expert] evidence"); *Hydrogen Peroxide*, 552 F.3d at 323 (reversing certification where district court failed to weigh competing expert evidence); *see also Comcast Corp. v. Behrend*, 569 U.S. 27, 36 (2013) (explaining that the predominance requirement would be "reduce[d] … to a nullity" if "at the class-certification stage, *any* method of measurement is acceptable so long as it can be applied classwide, no matter how arbitrary the measurements may be").

The Supreme Court's decision in *Halliburton* is instructive. There, the Court held that the factual prerequisites necessary to establish a presumption of reliance on fraudulent representations "must be proved before class certification" in securities class actions. 573 U.S. at 282-83. Proof of those prerequisites is "an essential precondition" for certification of securities class actions because, absent a presumption of reliance, "[e]ach plaintiff would have to prove reliance individually, so common issues would not predominate over individual ones." *Id.* at 281-82. Likewise here, Comanor's estimates are "an essential precondition" for class certification because if those estimates are wrong, Plaintiff's purported common

proof of reliance and causation "completely collapses," and each class member would have to prove those issues individually. *See id*. at 282-83.

It makes no difference that the district court found Comanor's evidence admissible under *Daubert*. "Courts have frequently found that expert evidence, while otherwise admissible under *Daubert*, was inadequate to satisfy the prerequisites of Rule 23," including in cases "where the evidence contained unsupported assumptions" or "was inadequate to prove an element of the claim for the entire class." *Olean*, 31 F.4th at 666 n.9. As a result, "a district court errs when it 'limits its analysis of [predominance] to a determination of whether Plaintiffs' evidence on that point was admissible.'" *Graditsky v. Am. Honda Motor Co.*, 957 F.3d 979, 986 (9th Cir. 2020) (quoting *Ellis*, 657 F.3d at 982). "Instead, the district court must engage in a rigorous analysis" of competing expert evidence "rather than merely concluding that, because [the plaintiff's] evidence was admissible, a finding of [predominance] was appropriate." *Id*. (cleaned up); *see also Ellis*, 657 F.3d at 982-84 (vacating class certification where district court "seemed to end its analysis of the plaintiffs' evidence after determining such evidence was merely admissible"); *Hydrogen Peroxide*, 552 F.3d at 323 (expert testimony "should not be uncritically accepted as establishing a Rule 23 requirement merely because the court holds the testimony should not be excluded."). No such rigorous analysis occurred here.

C. A "rigorous analysis" confirms that Comanor's analysis cannot resolve causation and injury on a classwide basis.

If the district court had conducted the rigorous analysis required by this Court's precedent, it could not have concluded that Comanor's estimates provide viable common proof of classwide injury and causation. Those estimates rest on the same type of simplistic market-share extrapolation that courts in similar cases have rejected as insufficient to satisfy the predominance requirement. They also fail to support class certification because they rely on false and unsubstantiated assumptions that merely relabel the critical individualized inquiries that remain necessary to establish causation and injury.

1. Comanor's simplistic market-share extrapolation cannot establish classwide causation and injury.

One consequence of the district court's failure to conduct a rigorous analysis of Comanor's estimates is that the court completely misunderstood the basis for those estimates. The court mistakenly assumed that Comanor used "an econometric regression model" with an "R-squared value of 99%" to estimate that 56.7% of Actos prescriptions were fraudulently induced.[3] *See* 1-ER-8-9, 21-22. But Comanor did not, in fact, use an "econometric regression model" to generate that estimate.

[3] A regression model is a econometric model that, when properly constructed, "enables one to uncover the relationship between a dependent variable"—here, the number of Actos prescriptions—and "one or more explanatory variables"—here, the supposed deceit. Am. Bar. Ass'n, *Proving Antitrust Damages* § II.6 (3d ed. 2017).

Instead, he derived it from an unsubstantiated assumption that, if not for the alleged disclosure failures, Actos's market share during the entire class period (June 1999 through September 2010) would have been the same as its market share in December 2013, which on average was 57% lower than during the class period. Unaware of the true basis of Comanor's 57% estimate, the district court failed to recognize that this type of "simplistic extrapolation" fails as a matter of law to provide viable common proof of classwide RICO causation. *See, e.g.*, *Sergeants*, 806 F.3d at 90-92; *Zyprexa*, 620 F.3d at 133-36.

There are two distinct steps in Comanor's analysis. At the first step, Comanor used regression models, but only to make a narrow background claim that the rate of Actos prescriptions declined to some extent following the FDA's September 2010 announcement that it was reconsidering the risks of taking Actos. *See, e.g.*, 3-ER-377-78; 4-ER-525-28 (asserting that the regressions show that Actos prescriptions trended upwards until September 2010 and trended downwards thereafter). According to Comanor, his regressions show that the September 2010 announcement had *some* effect on the rate of Actos prescriptions, *see* 4-ER-525-31, but he does not claim that they quantify the *magnitude* of that effect or that they estimate the percentage of prescriptions that supposedly were fraudulently induced, *see* 3-ER-379-82.

Comanor turned to those critical questions at the all-important second step of his analysis. At that step, Comanor used a crude market-share extrapolation to try to estimate the percentage of prescriptions that allegedly were fraudulently induced. He began by selecting December 2013—over three years after the FDA's September 2010 announcement—as the date on which he assumes physicians were fully informed about the risks of Actos. 4-ER-532. Next, he estimated that in December 2013, pioglitazone's share of the diabetic drug market was 4.72%, which is roughly 57% lower than its average market share during the class period (July 1999 to September 2010). 4-ER-533, 539; 3-ER-335, 382-83. Finally, he assumed that the *entire* difference between pioglitazone's December 2013 market share and its market share during the full 11-year class period is attributable to the alleged misconduct, *i.e.*, he assumed that *nothing else* explained or contributed to the 57% decline in average market share. 3-ER-386-87, 407-09. On that meager basis, Comanor inferred that the alleged disclosure failures generated 57% of Actos prescriptions during the class period. *See* 3-ER-410; *see also* 3-ER-400-01; 4-ER-539-41; 1-ER-22 & n.90.

Comanor had no evidentiary basis whatsoever for his key assumption that the alleged disclosure failures, standing alone, accounted for every single Actos prescription written over the course of the proposed class period in excess of Actos's December 2013 market share. To the contrary, he acknowledged at his deposition

that this assumption is wrong: he agreed that "the market changed a lot" from 1999 to 2013, 3-ER-264, and that the decline in Actos sales after the September 2010 FDA announcement was not entirely "due to the dissemination of information" about bladder cancer risk, 3-ER-265-66. Similarly, defense expert Dr. James Hughes identified several market factors wholly unrelated to the alleged disclosure failures that explain the decline in Actos's market share, including "the introduction of new type-2 diabetes treatment options, the launch of generic drugs, changes in safety information for competing therapies … , changes in drug prices, the introduction of new insurance plans … , and changes to treatment guidelines." 3-ER-386; *see also* 3-ER-374-75, 382-83, 386-88, 408-11. Yet another unrelated factor that contributed to the decline in market share was the FDA's 2007 warning that Actos is associated with a heightened risk of congestive heart failure, a risk Defendants are not accused of concealing.[4] Finally, Comanor's 57% estimate rests on the far-fetched assumption that *everything* that was known about potential bladder cancer risks in December 2013 should have been fully disclosed in July 1999, *see* 3-ER-268-69, even though most of the relevant scientific research available in 2013 did not even *exist* until well into the 2000s. *See supra* p.11.

[4] *See* 3-ER-343-44, 380, 383 n.168, 385-86, 386-88, 407-11; 3-ER-267-69 (admitting that Actos prescriptions declined following the 2007 warning); 4-ER-545 (showing a decline in Actos prescriptions following 2007 FDA warning).

In short, Comanor made no attempt to account for *any* other factors in his extrapolation from Actos's December 2013 market share. He simply assumed that in each of the 135 months between July 1999 and September 2010, Actos would have had exactly the same market share as it commanded in December 2013 following (i) the introduction of new treatment options, (ii) the availability of generic alternatives, (iii) the disclosure of unrelated cardiac risks, and (iv) the substantial changes to the insurance landscape including the passage of the Affordable Care Act. Comanor's extrapolation is thus incapable of providing common answers to the individualized questions of causation and injury. *See, e.g.*, *Sergeants*, 806 F.3d at 89-90; *Zyprexa*, 620 F.3d at 135-36.

The Second Circuit's decisions in *Zyprexa* and *Sergeants* confirm the flaws of this approach. In both those RICO class actions, the plaintiffs alleged that the defendants fraudulently induced TPPs to pay for larger quantities of prescription medicines than they otherwise would have. *See Sergeants*, 806 F.3d at 74; *Zyprexa*, 620 F.3d at 129. In addition, in both cases, the plaintiffs relied on simplistic market-share extrapolations to try to provide "generalized evidence" of classwide RICO causation: the *Sergeants* plaintiffs relied on "evidence showing that sales of [the drug] Ketek dropped precipitously after the FDA's public health advisory and Ketek's label revisions in 2006," 806 F.3d at 91, and the *Zyprexa* plaintiffs "primarily offered evidence that the number of Zyprexa prescriptions fell after the

drug's … side effects were disclosed by a revision to its label in 2003," *id*. at 89-90 (quoting *Zyprexa,* 620 F.3d at 128). In both cases, however, the Second Circuit held that the plaintiffs failed to satisfy Rule 23(b)(3)'s predominance requirement because mere evidence that market shares fell following an FDA warning "was insufficient to show class-wide RICO causation" and "was not enough … to prove that each class member was injured by [the defendant's] alleged misrepresentations, in light of the multifaceted and individualized nature of physicians' prescribing decisions." *Sergeants*, 806 F.3d at 92.

The same analysis applies here. Like the experts in *Zyprexa* and *Sergeants*, Comanor relied on a false and unsubstantiated assumption that, "but for [the defendants'] alleged misrepresentations, sales of [the medication at issue] would never have risen above the number of sales [that were made] after more accurate information about [the medication's] side effects became public." *Zyprexa*, 620 F.3d at 135. Moreover, like the experts in those two cases, Comanor "made no attempt to control for ... other [market] factors" or to isolate changes in the medication's market share "actually attributable to the safety disclosures, as opposed to other factors." *Sergeants*, 806 F.3d at 92. Thus, like the expert evidence offered in those two cases, Comanor's "simplistic proof" is incapable of establishing classwide RICO causation. *See id*. at 90, 95-97.

Without acknowledging that Comanor used a simplistic market-share extrapolation rather than a regression to generate his 57% estimate, the district court cited *Neurontin*, 712 F.3d at 30, to support its mistaken conclusion that "*a statistical regression, like Comanor's analysis*, can establish but-for causation for a civil RICO claim." 1-ER-26. Unlike Comanor, however, the plaintiff's expert in *Neurontin* used a regression model that accounted for other market factors—not a crude market-share extrapolation—to estimate the percentage of prescriptions that allegedly were fraudulently induced. *See* 712 F.3d at 30, 46. Comanor's crude extrapolation "is akin to the simplistic proof introduced by the *Zyprexa* plaintiffs, and not to the far more sophisticated proof offered in *Neurontin*." *Sergeants*, 806 F.3d at 96-97 (distinguishing the *Neurontin* regressions from a mere "extrapolation from the fact that the number of … prescriptions … fell after [the defendant's] fraud became known"). Furthermore, the *Neurontin* expert offered her regression model to prove causation only for a single health care provider. *See Neurontin*, 712 F.3d at 30, 46. Here, by contrast, Plaintiff offers a simplistic extrapolation to prove causation for a class of *thousands* of TPPs, and that extrapolation "does not furnish a sound basis to find causation on a class-wide basis." *Sergeants*, 806 F.3d at 95.

2. Comanor's "independent prescription" assumption cannot withstand rigorous analysis.

A second fatal defect in Comanor's estimates is that they simply trade one predominance problem for another: they purport to provide common proof of

classwide injury and causation *only* if accompanied by a mountain of individualized evidence proving that *each* of the thousands of proposed class members paid for five "independent" Actos prescriptions. Plaintiff's indispensable need for this individualized evidence itself defeats predominance.

As Plaintiff recognized in the proceedings below, there is a wide gap between Comanor's initial estimate that 57% of Actos prescriptions were fraudulently induced and the conclusion that the alleged disclosure failures injured each individual class member. To try to close that gap, Plaintiff offered Comanor's calculation that if a class member paid for five "independent" prescriptions, there is a 98.5% chance it paid for a fraudulently-induced prescription. *See* 1-ER-22 & n.90.[5]

Comanor's 98.5% calculation, however, cannot be applied to any individual TPP—let alone a class of thousands of them—unless and until Plaintiff *proves* Comanor's threshold assumption that each of those TPPs paid for five or more "independent" prescriptions. And proving that assumption requires the very type of individualized inquiry into specific doctors, prescriptions, and TPPs that "makes general proof of but-for causation impossible." *See Zyprexa*, 620 F.3d at 135. Indeed, both sides' experts agree that fact-intensive individual inquiries would be

[5] "Taking Comanor's summary statistics as valid, the chance that a TPP paid for five Actos prescriptions—and that none was induced by fraud—would be $(1 - 0.5677)^5$, or about 1.5%." 1-ER-22 n.90.

necessary to determine which prescriptions were independently written. To see why, consider a doctor who writes a dozen prescriptions for a dozen different patients. In writing each prescription, the doctor necessarily relies on her own particular background, experience, knowledge, and comfort with a particular medicine—all of which is common to all her prescriptions. 3-ER-368-69. In other words, there are common factors between the prescriptions that alter the probability that each will or won't be written. Comanor thus admitted that, to determine whether "prescriptions written by the same physician [are] independent," the factfinder "would need to know a lot more about prescribing habits and how physicians treat different patients." 3-ER-319-20. He further admitted that "you'd have to do a study of that type of behavior" and that he could not "answer" whether such prescriptions "are independent for some physicians but not for others." 3-ER-320. Ultimately, "if you want to assess whether a third-party payer reimbursed for five or more independent Actos or pioglitazone prescriptions," "[y]ou have to determine if they're independent." 3-ER-320-21.

These "independence" issues, moreover, extend well beyond prescriptions written by the same physician. Consider a group of physicians within the same medical practice who reviewed the same materials, shared information with each other, and wrote Actos prescriptions based on common considerations. The decision of one physician in the group to write (or not write) Actos prescriptions lacks

independence from the decisions of her colleagues. *See* 3-ER-368-69. Put another way, Actos prescriptions are not handed out at random; they are written by doctors affiliated with particular medical practices that bring their own distinct blend of knowledge, experience, and risk assessments to bear in deciding which medications to prescribe. As a result, prescriptions that still would have been written in Plaintiff's but-for world are likely to be clustered among particular doctors and medical practices and their affiliated TPPs—not strewn at random throughout the class. *See* 3-ER-368-69. This in turn means that even assuming Comanor is correct that 57% of Actos prescriptions were fraudulently induced (and he is not), his 98.5% estimate is overstated and masks an unknown number of uninjured class members.

Plaintiff thus faces an insurmountable dilemma. It cannot rely on Comanor's 98.5% estimate as purported "common proof" of causation and injury unless it proves each putative class member paid for at least five independent Actos prescriptions. Yet Plaintiff has no means of proving this essential premise of Comanor's probability estimates short of conducting thousands of fact-intensive inquiries into the prescribing practices of individual doctors. Just as these physician-specific inquiries "make[] general proof of but-for causation impossible," *Zyprexa*, 620 F.3d at 135, they ensure that individual inquiries would predominate over common ones at trial, *see, e.g.*, *id.*; *Rail Freight II*, 934 F.3d at 627 (individual inquiries predominated where "at least 2,037 individual determinations of injury and

causation" would be necessary); *Van*, 61 F.4th at 1069 (vacating certification where plaintiff failed to show that "a class-member-by-class-member assessment of the individualized issue will be unnecessary or workable").

The district court breezed past this problem largely by taking Comanor's estimates "at face value." 1-ER-22 n.88. Its entire discussion of this issue consisted of a single cursory paragraph in which it suggested that plan-level data published by a third-party (IQVIA) could be used to "screen out" prescriptions that were "merely for refills." 1-ER-23. But prescriptions written by the same doctor or medical practice are not independent of each other just because they are not refills, *see* 3-ER-363-69, and the "rudimentary claims data" cited by the district court identifies refill prescriptions alone.[6] Merely screening out refills does nothing to fulfill Comanor's threshold assumption of independence, which applies only if one prescription decision in no way "alter[s] the probability of the same outcome in another claim." 3-ER-319-20; *see also* 4-ER-539-40.

In the end, Plaintiff's "five independent prescriptions" gambit only shuffles a fatal predominance problem from one compartment to another. For this reason, too, certification was reversible error.

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[6] *See* 1-ER-23 n.96; Dkt. 310, Pl.'s Supp. Br. 10:1-9 (citing Dkt. 260-1, Pl.'s Sealed Class Cert. Reply 11:14-21); 3-ER-221, 398-99, 467 n.3. Furthermore, these data cover only "October 2006 through September 2010," which is less than half of the class period. 3-ER-221.

3. Comanor's alternative treatment assumption cannot withstand rigorous analysis.

Comanor's probability estimates are further skewed by his admittedly false assumption that *none* of the fraudulently-induced prescriptions he purports to quantify would have been replaced by more expensive treatment options in the but-for world. A TPP's ability to "show[] injury" depends on "what the alternatives to an 'excess' prescription would have been," because a physician who declined to prescribe Actos because of bladder cancer concerns "likel[y]" would have written a "substitute prescription" that could have been more expensive. *See Zyprexa*, 620 F.3d at 135-36. Comanor's 98.5% estimate assumes away this problem by assuming that *every single excess prescription*— "all of them"—would have been replaced by the same less-expensive medication—metformin—in the but-for world. 3-ER-310.

This assumption blinks reality. Even Comanor admits that it "seems unlikely" that "no other drug besides metformin would be used." 3-ER-310. Moreover, uncontroverted evidence shows that "many patients" "who discontinued Actos during the damages period" "switch[ed] to alternative drugs that cost the same or more to the TPP and to the patient." 3-ER-331; *see also* 3-ER-238; 1-ER-23-24. In fact, only 17% of patients who discontinued Actos during the relevant period switched to metformin, while more than 30% switched to alternative treatments, many of which were as expensive or more expensive than Actos. 3-ER-404-06. That is presumably because Actos ordinarily was prescribed (i) *after* a patient was

unable to control their diabetes with metformin, 3-ER-403-04, (ii) to patients who cannot take metformin, 3-ER-398, or (iii) in combination with metformin, 3-ER-343. *See also* 1-ER-24 n.98 ("[P]atients usually start with a different drug, like Metformin, before trying Actos."). Indeed, in Comanor's own telling, "[m]etformin is the *first line* pharmacological treatment for Type 2 diabetes," 4-ER-537 (emphasis added), so there is no reason to assume that the "70[%] of patients [who] had already tried metformin prior to initiating Actos" would have reverted to a prior medication that had proven ineffective. 3-ER-331, 397-98.

Comanor's faulty metformin assumption is yet another reason why his estimates "contain[] unsupported assumptions" that render them incapable of "resolving a class-wide issue in one stroke." *Olean*, 31 F. 4th at 666 n.9. Comanor's far-fetched assumption that *no* Actos prescriptions would have been replaced by more expensive treatments in the but-for world inflates his injury estimates and masks the need for individualized inquiries into the alternative medications that particular doctors would have prescribed for particular patients. As *Zyprexa* recognized, those individualized inquiries preclude "showing injury by general proof." 620 F.3d at 135.

The district court sidestepped these individual inquiries by flipping the burden to Defendants "to identif[y] how many TPPs are (or would be) affected" by more expensive treatment alternatives rather than holding Plaintiff to its burden of proof.

1-ER-23-24. That gets the inquiry backward. To prove classwide RICO injury, Plaintiff must show that each class member suffered a "concrete financial loss," *Chaset v. Fleer/Skybox Int'l, LP*, 300 F.3d 1083, 1086-87 (9th Cir. 2002), which requires proving either that "*no* medication would have been prescribed" instead of Actos or that "possible alternatives … would have been less expensive," *Zyprexa*, 620 F.3d at 135-36.[7] But despite acknowledging that TPPs "that would have paid more for an alternative treatment" are "uninjured," that "doctors prescribed more expensive alternatives," and that it was "unknown" "[h]ow those patients are distributed across the class of TPPs," the district court faulted Defendants for failing to *disprove* the court's speculation "that [these] switching costs may affect only a de minimis number of TPPs." 1-ER-24.

That was legal error because the burden is on *Plaintiff* to "affirmatively demonstrate [its] compliance" with Rule 23. *Wal-Mart*, 564 U.S. at 350. But even putting that error aside, the court's speculation that switching costs might have injured only "a few class members" flies in the face of the facts of the case. 1-ER-

[7] Although the district court initially recognized that TPPs "that would have paid more for an alternative treatment" are "uninjured," it later asserted that TPPs with no "net economic loss" still suffered "injury-in-fact" if they paid for excess prescriptions. 1-ER-23, 25. But the case cited for that proposition addressed Article III injury, not RICO injury. 1-ER-25 (citing *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012)). RICO's requirement of injury to "business or property" requires "concrete financial loss," so pretended "disappointment" about having *saved* money is insufficient. *Chaset*, 300 F.3d at 1087.

25. The proposed class includes large numbers of TPPs that paid for very few Actos prescriptions—indeed, Comanor's preliminary analysis indicates that, among the "plans reporting new prescriptions" during the class period, over six hundred could not even scrape together "five prescriptions" in total, let alone five "independent" prescriptions. 1-ER-222. Thus, even one prescription that would have been replaced by a more expensive "alternative[]" can make all the difference to whether a plan purportedly was injured. *Zyprexa*, 620 F.3d at 135.

II. The District Court Erred By Disregarding Defendants' Individualized Challenges To Causation And Injury In Its Predominance Analysis.

The district court committed an independent error by certifying a class despite acknowledging that "[i]t remains an open question whether a class of TPPs may successfully leverage common evidence … without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones." 1-ER-28. The court recognized that Defendants have a right to raise individualized challenges to Plaintiffs' purported showing of classwide causation and injury and that these challenges create "a real and significant risk … that individualized factual determinations would swamp common ones." 1-ER-29. The prospect of these individualized disputes doomed the proposed consumer class, 1-ER-44, and should have doomed the TPP class as well. The district court's contrary holding rests on errors of law.

A. Defendants' individualized challenges to causation and injury will predominate at trial.

In assessing whether common questions will predominate over individual ones, courts must consider not only the plaintiff's affirmative case, but also any individualized defenses the defendants are entitled to raise. *See, e.g.*, *Wal-Mart*, 564 U.S. at 367 ("[A] class cannot be certified on the premise that [a defendant] will not be entitled to litigate its statutory defenses to individual claims."); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 55, 58 (1st Cir. 2018) ("[T]he defendant must be offered the opportunity to challenge each class member's proof that the defendant is liable to that class member."); *id.* at 58 ("[A] class cannot be certified based on an expectation that the defendant will have no opportunity to press at trial genuine challenges to allegations of injury-in-fact."). Accordingly, it is not enough for Plaintiff to demonstrate that *it* will rely on generalized proof of its claims; rather, Plaintiff must also show that common questions will predominate even after accounting for the individualized defenses *Defendants* will raise.

Plaintiff has not made and cannot make that showing. Although Plaintiff will rely on Comanor's probability estimates to try to prove that nearly all class members paid for at least one fraudulently-induced prescription, Defendants will not limit themselves to using generic probability estimates in opposition. Instead, as the district court recognized, Defendants are entitled to "depose individual prescribing physicians to contest Plaintiffs' theory of but-for causation, as those physicians

might testify that they would have continued to prescribe Actos, notwithstanding the bladder cancer risk," and the "trier of fact could … rely on the physicians' testimony to qualify, discredit, or reject Plaintiffs' common evidence of but-for causation." 1-ER-29; *accord Neurontin*, 712 F.3d at 45-46 (recognizing that doctor-by-doctor testimony should be considered even when aggregate statistical evidence is offered); *Zyprexa*, 620 F.3d at 136 ("Plaintiffs cannot use generalized proof [to show causation] when individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all ….").

The district court explicitly recognized this "key flaw with Plaintiffs' predominance argument," adding that because there are "so many individual TPPs in the class," there is "a real and significant risk … that individualized factual determinations would swamp common ones on the question of but-for causation." 1-ER-29. The court thus acknowledged that "*[i]t remains an open question*" whether Plaintiffs "may successfully leverage common evidence of the kind offered here … *without running into so much individualized analysis that individual questions of fact begin to overwhelm the common ones*." 1-ER-28 (emphases added); *see also* 1-ER-30 (concluding that the state of the evidence on predominance was "not clear"). That should have been the end of the predominance inquiry. Plaintiff bore the burden of proving predominance "before class certification," *Olean* 31 F.4th at 664-65, and it failed to do so because, even now, "[i]t remains an

open question" whether individual questions of fact will "overwhelm the common ones." 1-ER-28.

B. The district court's contrary conclusion rests on errors of law.

In nonetheless certifying a class, the court committed at least two errors of law.

First, the court shifted the burden to Defendants to *disprove* predominance, granting certification where the impact of individualized defenses was "not clear" and predominance "remain[ed] an open question." 1-ER-28, 30. That was error not only because "the plaintiff bears the burden of proving that class issues predominate over individualized issues," *Van*, 61 F. 4th at 1067 n.11, but also because, under the 2003 amendments to Rule 23, "[a] court that is not satisfied that the requirements of Rule 23 have been met should refuse certification until they have been met." Fed. R. Civ. P. 23(c)(1), Advisory Committee Note (2003). The 2003 amendments "eliminated the language that had appeared in Rule 23(c)(1) providing that a class certification 'may be conditional.'" *In re Hydrogen Peroxide*, 552 F.3d at 319. The purpose of that amendment was "'to avoid the unintended suggestion, which some courts have adopted, that class certification may be granted on a tentative basis, *even if it is unclear that the rule requirements are satisfied*.'" *Id*. (quoting Report of the Judicial Conference Committee on Rules of Practice and Procedure 10 (2002) (emphasis added)). That is exactly what happened here: the district court certified

a class despite finding that "one might conclude that individualized questions of fact predominate over common question," that it was "premature" to determine that question, and that it was "not clear" and an "open question" whether individualized issues would predominate over common ones. *See* 1-ER-28, 30.

Second, having flipped the burden of proof against Defendants, the court found that Defendants did not meet it based on the same "misunderstanding of the Rule 23 inquiry" that led this Court to vacate the certification order in *Van*. 61 F.4th at 1068. In *Van*, the defendant opposed class certification by providing "evidence that at least eighteen of the 13,680" class members were subject to an individualized defense. *Id*. The district court dismissed those examples as "de minimis" and certified a class, but this Court disagreed, finding that regardless of whether the defendant provided "two or eighteen examples" of its individualized defense, those examples "substantiated the individualized issue" and "summon[ed] the spectre of class-member-by-class-member adjudication." *Id*. at 1068-69 & n.12. This Court thus remanded for an assessment of "whether a class-member-by-class-member assessment of the individualized issue will be unnecessary or workable." *Id*. at 1069.

Likewise here, Defendants substantiated their individualized defenses by providing deposition testimony from the providers who treated the consumer class representatives, both of whom testified that they continued prescribing Actos after the date when Plaintiff admits the alleged cancer risks were fully disclosed, *see* 1-

ER-31; 2-ER-63; 2-ER-67-68. Those representative examples were more than enough to "substantiate the individualized issue[s]," *Van*, 61 F.4th at 1068 n.12, because even Plaintiff concedes that *over 40% of Actos prescriptions*—millions of prescriptions written by thousands of doctors—still would have been written "even if full information of the risks was known." 1-ER-39; *see also* 4-ER-553 (reflecting over 100 million unaffected prescriptions from 1999 through 2010). The district court nevertheless dismissed those examples as insufficient to disprove predominance based on a simplistic "tally" of the evidence each side deposited into the class certification record. 1-ER-31. Observing that Defendants provided only two representative examples of their individualized defenses at the class certification stage, the court held that, "[a]s the tally stands, individualized issues would not predominate … if the trial was held *today*." *Id*.

That reasoning repeats the error that led to reversal in *Van*. Contrary to the district court's assumption, class action defendants are not required to "collect and introduce at the certification stage all of the evidence on which [they] would rely in the merits phase." *Bais Yaakov of Spring Valley v. ACT, Inc.*, 12 F.4th 81, 105 (1st Cir. 2021) (Barron, J., concurring). Nor does it matter "whether [defendants] provide[] two or eighteen examples" of their individualized defenses at the certification stage. *Van*, 61 F.4th at 1068 n.12. What matters is whether the defendant does enough to "summon[] the spectre of class-member-by-class-member

adjudication." *Id*. at 1069. Defendants indisputably did that here: all agree that Defendants are entitled to depose and call as witnesses the thousands of doctors who still would have written Actos prescriptions—or who would have written even more expensive prescriptions—in Plaintiff's but-for world. Plaintiff thus bore the burden of "prov[ing] by a preponderance of the evidence" that, despite these looming individualized defenses, "class-member-by-class-member adjudication will be unnecessary or workable." *Id*. at 1069. No such proof was ever provided.

Although the district court cited *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442 (2016), in support of its contrary approach, *see* 1-ER-30, *Tyson* reinforces the conclusion that class certification depends on a forward-looking assessment of what the trial will look like, not a mere tally of the evidence as it stands in the certification record. *Tyson* was an FLSA class action in which "an evidentiary gap created by the employer's failure to keep adequate records" shifted the burden of proof against the employer and foreclosed any prospect that individualized disputes would predominate over common ones. 577 U.S. at 456-57. Moreover, *Tyson* arose in a post-trial setting, and unsurprisingly, rather than relying on individualized defenses at trial, the defendant relied on the "common" defense that *no* class member was capable of proving its claims. *Id.* at 457. Here, by contrast, no trial has occurred, individualized evidence is readily available, and the district court's task was thus to *predict* how the issues will play out when the case is ready for trial. *See Van*, 61

F.4th at 1069; *Lamictal*, 957 F.3d at 190 ("[A] district court must formulate some prediction as to how specific issues will play out in order to determine" predominance). The court never did so.

III. The District Court Erred By Certifying A Class Without Any Common Evidence Capable Of Identifying Unharmed Class Members.

The district court committed a third reversible error by certifying a class notwithstanding the vast numbers of individual inquiries that will be necessary to distinguish uninjured class members from allegedly injured ones. Although Plaintiff asserts that the class contains only a "de minimis" number of uninjured TPPs (Dkt. 258, Pl.'s Class Cert. Reply 9:23-25), it does not dispute that at least *some* class members were uninjured. Because these unharmed TPPs cannot prevail on the merits, Plaintiff bears the burden of demonstrating that all such unharmed class members can be identified through a process that "does not cause individual inquiries to overwhelm common issues." *Asacol*, 907 F.3d at 58. Plaintiff, however, has no means of identifying unharmed class members short of conducting full-blown, individual trials on causation and injury questions. That alone should have defeated predominance. *See id.*; *Rail Freight II*, 934 F.3d at 625.

A. Plaintiff lacks a feasible means of identifying unharmed TPPs.

Article III and RICO both prohibit unharmed class members from obtaining any relief in this action. "Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not." *TransUnion LLC v. Ramirez*,

141 S. Ct. 2190, 2208 (2021) (cleaned up). Injury-in-fact is also an element of liability in civil RICO actions. *See* 18 U.S.C. § 1964(c) (claim may be brought by those "injured in [their] business or property"); *Shulman v. Kaplan*, 58 F.4th 404, 409-10 (9th Cir. 2023) (civil RICO claims require "injury to … business or property"). Certification of a class does not excuse individual class members from their obligation to prove injury-in-fact at the liability stage because "Rule 23's requirements must be interpreted in keeping with Article III constraints, and with the Rules Enabling Act, which instructs that rules of procedure 'shall not abridge, enlarge, or modify any substantive right.'" *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997) (quoting 28 U.S.C. § 2072(b)).

"Uninjured class members cannot prevail on the merits, so their claims must be winnowed away as part of the liability determination." *Rail Freight II*, 934 F.3d at 625. Moreover, "any winnowing mechanism must be truncated enough to ensure that the common issues predominate, yet robust enough to preserve the defendants' Seventh Amendment and due process rights to contest every element of liability and to present every colorable defense." *Id.* at 626; *see also Olean*, 31 F.4th at 668 ("When individualized questions relate to the injury status of class members, Rule 23(b)(3) requires that the court determine whether individualized inquiries about such matters would predominate over common questions.").

This leaves Plaintiff with two options: it may either (i) "prove, through common evidence, that all class members were in fact injured," *In re Rail Freight Fuel Surcharge Antitrust Litig.* (*Rail Freight I*), 725 F.3d 244, 252 (D.C. Cir. 2013), or (ii) prove that unharmed class members can be "winnow[ed] away" without fact-intensive individual inquiries, *Rail Freight II*, 934 F.3d at 624-25. There is no third option to kick the can down the road. Plaintiff must "affirmatively demonstrate" that predominance is satisfied at the certification stage. *Wal-Mart*, 564 U.S. at 350.

Plaintiff concedes that it cannot avail itself of the first option, *i.e.*, proving that *all* class members were injured. Although the parties disagree as to *how many* TPPs were unharmed, all agree that at least *some* were uninjured, either because they did not reimburse any "fraudulently-induced" prescriptions, avoided paying for more expensive alternatives, or both. *See, e.g.*, Dkt. 258, Cert. Reply 9:23 (asserting that only a "de minimis" number of class members were uninjured); *see also* 1-ER-22 (concluding that there "appear[] to be" uninjured class members and that "it is not known at this time which specific TPPs managed to avoid paying for any fraudulently induced prescriptions").

Plaintiff's only option was thus to provide a mechanism for identifying all unharmed TPPs that is "truncated enough to ensure that the common issues predominate, yet robust enough to preserve the defendants' Seventh Amendment and due process rights." *Rail Freight II*, 934 F.3d at 625. But rather than providing

such a mechanism, Plaintiff conceded that "*it is true it will take individual inquiry to determine if an individual TPP was injured*." Dkt. 258, Cert. Reply 11:10-11 (emphasis added). The district court likewise acknowledged that identifying unharmed TPPs "would likely turn on individualized evidence" because Comanor's evidence does not identify "which specific TPPs managed to avoid paying for any fraudulently induced prescriptions." 1-ER-22. That alone should have defeated predominance. *See, e.g.*, *Rail Freight II*, 934 F.3d at 624-26; *Asacol*, 907 F.3d at 57-58.

Rail Freight II and *Asacol* are instructive. In *Asacol*, the plaintiffs' expert conceded that the class included unharmed members who would have continued purchasing the medication at issue in the but-for world. 907 F.3d at 51. Although the district court certified a class despite the presence of these unharmed class members, the First Circuit reversed, reasoning that the plaintiffs lacked any means of efficiently identifying these unharmed class members. *Id*. at 57-58. The court held that class-member affidavits could not be used to identify uninjured class members because the defendants had a right to challenge those affidavits at trial. *Id*. at 54. The court also held that expert evidence showing a 90% probability of injury to any given class member was insufficient because that evidence "leads to the demonstrably wrong conclusion that one hundred percent of individuals were injured." *Id*. The court thus concluded that individual testimony would be needed

to separate the injured from the uninjured and reversed the certification order on that basis. *Id*. at 57-58.

Similarly, in *Rail Freight II*, the plaintiffs relied on a regression model to prove classwide injury, but the model estimated that a minority of class members were uninjured, and plaintiffs "proposed no further way—short of full-blown, individual trials—to reduce this number and segregate the uninjured from the truly injured." 934 F.3d at 621-25. The D.C. Circuit thus reasoned that testimony from "thousands of class members" would be necessary to ensure that no unharmed class members prevailed on liability, and declined to create the first case "allowing, under Rule 23, a trial in which thousands of class members testify." *Id.* at 627 (quoting *Asacol*, 907 F.3d at 57-58).

In *Olean*, this Court cited *Asacol* and *Rail Freight II* as examples of cases in which "the need to identify uninjured class members 'will predominate and render an adjudication unmanageable.'" 31 F.4th at 669 n.13 (quoting *Asacol*, 907 F.3d at 53-54 and citing *Rail Freight II*, 934 F.3d at 625). Here, just as in *Asacol* and *Rail Freight II*, there are at least *some* unharmed class members, and Plaintiff has "proposed no further way—short of full-blown, individual trials—to … segregate the uninjured from the truly injured." *Rail Freight II*, 934 F.3d at 625 (internal quotations omitted). No class can be certified under these circumstances.

B. Comanor's estimates cannot identify unharmed TPPs or avoid the need for individual inquiries into injury.

The district court recognized that "it is not known at this time which specific TPPs managed to avoid paying for any fraudulently-induced prescriptions" and that identifying these unharmed TPPs "would likely turn on individualized evidence." 1-ER-22. The court nonetheless concluded that Plaintiff satisfied the predominance requirement by offering Comanor's estimate that at least 98.5% of class members were injured. 1-ER-22. The court reasoned that if this 98.5% estimate is taken "at face value," then "Takeda and Lilly could dispute injury" for "only about 1.5% of the class," and individualized inquiries into injury are unlikely to predominate over common ones. 1-ER-22. That reasoning is incorrect for two main reasons.

First, even if Comanor's 98.5% estimate were correct, thousands of individual inquiries still would be necessary to determine which TPPs are among the 98.5% and which are among the 1.5%. Plaintiff concedes that Comanor's estimates cannot identify *which* TPPs were injured as opposed to *what percentage of TPPs* allegedly were injured. *See* Dkt. 258, Cert. Reply 11:10-11 ("[I]t is true it will take individual inquiry to determine if an individual TPP was injured."). Enormous numbers of individual inquiries therefore will be necessary to sort the wheat from the chaff. "Class members do not come pre-identified as [injured or uninjured], after all, and one does not ordinarily set out to find a needle in a haystack by examining only [1.5%] of the straw." *Asacol*, 907 F.3d at 61 (Barron, J., concurring).

The district court went wrong on this issue because it focused on the number of *unharmed class members* rather than the number of *individual inquiries* necessary to "segregate the uninjured from the truly injured." *Rail Freight II*, 934 F.3d at 625. As this Court explained in *Van*, the key question for purposes of the predominance requirement "is not whether a great number of plaintiffs will win or lose at trial on [an] individualized issue," but whether the individual inquiries necessary to separate winners from losers are "limited to a small number of class members." *Van*, 61 F.4th at 1067 n.11. Here, the number of individual inquiries that would be necessary is enormous: Plaintiff cannot distinguish uninjured TPPs from allegedly injured ones short of conducting individual causation and injury trials for *thousands* of TPPs. Class certification therefore should be reversed. *See id.*; *Bowerman v. Field Asset Servs.*, 60 F.4th 459, 469-71 (9th Cir. 2023) (reversing certification because "individualized injury and damages assessments" would be necessary); *Lara v. First Nat'l Ins. Co. of Am.*, 25 F.4th 1134, 1139 (9th Cir. 2022) (affirming denial of certification where "figuring out whether each individual putative class member was harmed would involve an inquiry specific to that person"); *Castillo v. Bank of Am., NA*, 980 F.3d 723, 731-32 (9th Cir. 2020) (affirming denial of certification where "determining liability for all class members would require complicated individualized inquiries").

Second, in finding that Defendants could dispute injury "for only about 1.5% of the class," 1-ER-22, the district court simply *assumed* that Comanor's 98.5% estimate is correct. That was legal error. If the court wished to rely on Comanor's hotly-contested estimate to cap the number of disputes that are likely to arise at trial, then at a minimum it was required to *find*—not just assume—that this estimate more likely than not is accurate. *See Olean*, 31 F.4th at 665 ("[P]laintiffs must prove the facts necessary to [satisfy Rule 23] by a preponderance of the evidence[.]"). But the court made no such finding. Instead, it improperly assumed the truth of that estimate and refused to "prejudge its accuracy." *See* 1-ER-22 & n.88. Contrary to the district court's assumption, Comanor's mere contested *claim* that 98.5% of TPPs were injured provides no basis for capping the number of individualized disputes that Defendants can raise at trial.

For the reasons discussed above, those individualized disputes are legion. They range from disputes over which individual doctors wrote "fully informed prescriptions" that still would have been written in the but-for world, to which TPPs employed those doctors, to which prescriptions were and weren't "independent" of each other, to which patients would have switched to more expensive treatment options in Plaintiff's but-for world. *See supra* pp.28-42. Although the district court minimized the importance of these inquiries by speculating that there "may" be only a "de minimis" number of unharmed class members, 1-ER-23, 25, that reasoning

once again focuses incorrectly on the *number of unharmed TPPs* rather than the *number of individual inquiries* necessary to identify them. All uninjured class members must be identified, and Plaintiff has no means of doing so short of combing through the entire class.

IV. The Class Has Significant Superiority And Lilly-Specific Problems That Foreclose Certification.

A. Class proceedings are not a superior means of resolving this dispute.

The district court also erred by concluding that class-action litigation "is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). This standard is a rigorous one, and Plaintiff cannot meet it simply by asserting that "individual class members" are unlikely to pursue "small … individual damages." *Johannessohn v. Polaris Indus., Inc.*, 9 F.4th 981, 986 (8th Cir. 2021). Instead, Plaintiff "bears the burden of demonstrating" superiority, which includes accounting for "the difficulties likely to be encountered in the management of [the case]." *Zinser v. Accufix Rsch. Inst., Inc.*, 253 F.3d 1180, 1186, 1192 (9th Cir. 2001) (citation omitted). Although this issue of "[w]hether a class action will be manageable is, by far, the most critical concern in determining … superior[ity]," the court here devoted just half a page to the question, and erred in its analysis. *Lara*, 25 F.4th at 1138 (quotation omitted).

Plaintiff bore the burden of demonstrating superiority, *id.*, but the district court effectively excused Plaintiff from meeting that burden. Plaintiff simply promised that "there should not be any manageability problems" in its certification motion (Dkt. 229, Mot. 36:20-21), and then *completely* neglected superiority in its reply (*see* Dkt. 258). That is because Plaintiff has no "trial plan that would feasibly address" how to resolve claims and defenses for thousands of TPPs involving tens of millions of prescriptions. *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1278 (11th Cir. 2009). The strategy here is simply to leverage a $7 billion threat to extract a settlement that will avoid the coming judicial nightmare. But even that is too optimistic. As the district court recently recognized, there is "hornet's nest" of issues to resolve before this case makes it to trial, including "tricky" and "knotty issues to work through on many fronts including the identity of patients and identify of physicians and discovery from those nonparties." 2-ER-52, 53-54.

The district court tried to excuse Plaintiff's failure of proof by assuming that this case would require only "a five-week trial," but that assumption rests on a misunderstanding of the record. Defendants had pointed out that the *single-TPP* trial in *Neurontin* "'spanned five weeks' with 'twenty-one live witnesses and eighteen witnesses by deposition,'" Dkt. 247, Takeda's Class Cert. Opp'n 34:1-3, yet the district court nevertheless assumed that the trial in *this* case—involving *thousands* of TPPs—would take the same "five[] week[s]" it took to try *one* TPP's claim in

Neurontin. Those concerns cannot be waved away in a single paragraph reasoning that the "enormous logistical hurdles of a five-week trial" would be "preferable to many hundreds of shorter [trials]." 1-ER-15. "[T]he [district] court did not indicate that it has seriously considered the administration of the trial," so its "figure-it-out-as-we-go-along approach" requires reversal. *Robinson v. Tex. Auto. Dealers Ass'n*, 387 F.3d 416, 426 (5th Cir. 2004).

B. The claims against Lilly are especially unsuitable for class treatment.

The problems with the class are especially pronounced for Lilly. Plaintiff proposes litigating on a common class-wide basis Takeda *and* Lilly's liability for allegedly excess prescriptions between 1999 and 2010. But Actos is the Takeda Defendants' product, and Lilly stopped promoting it pursuant to a copromotion agreement in 2006, thus terminating any potential liability. *See Levine v. United States*, 383 U.S. 265, 266 (1966).

TPPs that reimbursed prescriptions after 2006 thus will need make *additional* individualized showings to establish their case against Lilly. That is because post-2006 decisions to prescribe (or not prescribe) Actos would have been driven by additional information entering the market—such as the critical 2007 Actos label change disclosing certain cardiac risks—as well as any new promotional efforts Lilly had nothing to do with. *Supra* p.31. The jury therefore will need to engage in yet another layer of physician-specific, individualized inquiry about whether factors

unrelated to Lilly influenced post-2006 prescriptions. For example, the prescriber for one of the patient-class representatives testified that, when she "deci[ded] to prescribe Actos in *2009*" to the patient, that choice "was *not* based upon any information from Eli Lilly." 2-ER-70 (emphases added). That prescription thus cannot serve as the basis of a claim against Lilly—and the same holds true for countless TPPs that reimbursed for similar post-2006 prescriptions. Litigating these individualized, prescriber-specific issues makes class treatment especially problematic.

The 2006 disjuncture also throws a wrench into Comanor's model of causation and injury. Consider Comanor's assertion that he can "identify[] which TPPs purchased, paid for, and reimbursed Actos prescriptions [without] individual inquiry" because "plan-level data provided by Defendants permits the tabulation of total new prescription[s] by plan and month from *October 2006 through September 2010*." 3-ER-221 (emphasis added). That assumption is useless as to the pre-2006 period relevant to Lilly, but it is necessary (though insufficient) for Comanor's five-independent-prescription theory. Moreover, Comanor's estimates of excess prescriptions vary from year to year, with the highest percentages occurring *after* 2006. 4-ER-553. That discrepancy further compounds all the difficulties of applying Comanor's model to small TPPs which reimbursed isolated prescriptions at specific times. Comanor did nothing to account for these issues; indeed, at his

deposition he was not even able to identify the time period that Lilly co-promoted Actos. 3-ER-322. But ignoring critical problems does not solve them, both as a matter of Plaintiff's affirmative case, as well as a matter of Lilly's individualized defenses.

CONCLUSION

The class certification order should be reversed.

January 19, 2024

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
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/s/ Andrew Soukup
Andrew Soukup

ADDENDUM

TABLE OF CONTENTS

RULES

Fed. R. Civ. P. 23(b)

(b) TYPES OF CLASS ACTIONS. A class action may be maintained if Rule 23(a) is satisfied and if:

* * *

(3) the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. The matters pertinent to these findings include:

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(f)

(f) APPEALS. A court of appeals may permit an appeal from an order granting or denying class-action certification under this rule, but not from an order under Rule 23(e)(1). A party must file a petition for permission to appeal with the circuit clerk

within 14 days after the order is entered, or within 45 days after the order is entered if any party is the United States, a United States agency, or a United States officer or employee sued for an act or omission occurring in connection with duties performed on the United States' behalf. An appeal does not stay proceedings in the district court unless the district judge or the court of appeals so orders.